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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,877	02/08/2002	Robert C. Downs	36-001810US	9765
22798	7590	08/26/2005	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/071,877	DOWNS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 June 2005.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 59-71 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-58 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Allowable Subject Matter***

The indicated allowability of claims 21 – 23, 45 – 47, 49 – 55 & 57 is withdrawn in view of the reference(s) to Yoshida et al. (U.S. Pat. No. 4,708,940), Alam et al. (U.S Pat. No. 5,792,050 A), Roginski et al. (U.S Pat. No. 4,927,545), Taylor (U.S Pat. No. 4,822,331) and Feldman (U.S Pat. No. 5,445,958 A). Rejections based on the cited reference(s) follow.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8 & 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: Claim 7 recites a "second motor." However, claims 1 and 5, upon which claim 7 is dependent, do not recite a *first* motor.

2. Claim 8 recites the limitation "first motor" in line 1. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 57 recites the limitation "fraction collector" in line 13. There is insufficient antecedent basis for this limitation in the claim.

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4. Claim 57 recites the limitation "sample receiving elements" in line 14. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 9, 14, 16, 19 – 21, 29 – 38, 42 – 44, 46, 48, 49, 53, 54, 57 & 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (U.S. Pat. No. 4,708,940) (hereinafter “Yoshida”).

Regarding claims 1, 9, 14, 16, 19, 20, 21, 32, 44, 48 & 58, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions (see col. 2, line 28 – col. 7, line 63; figure 6).

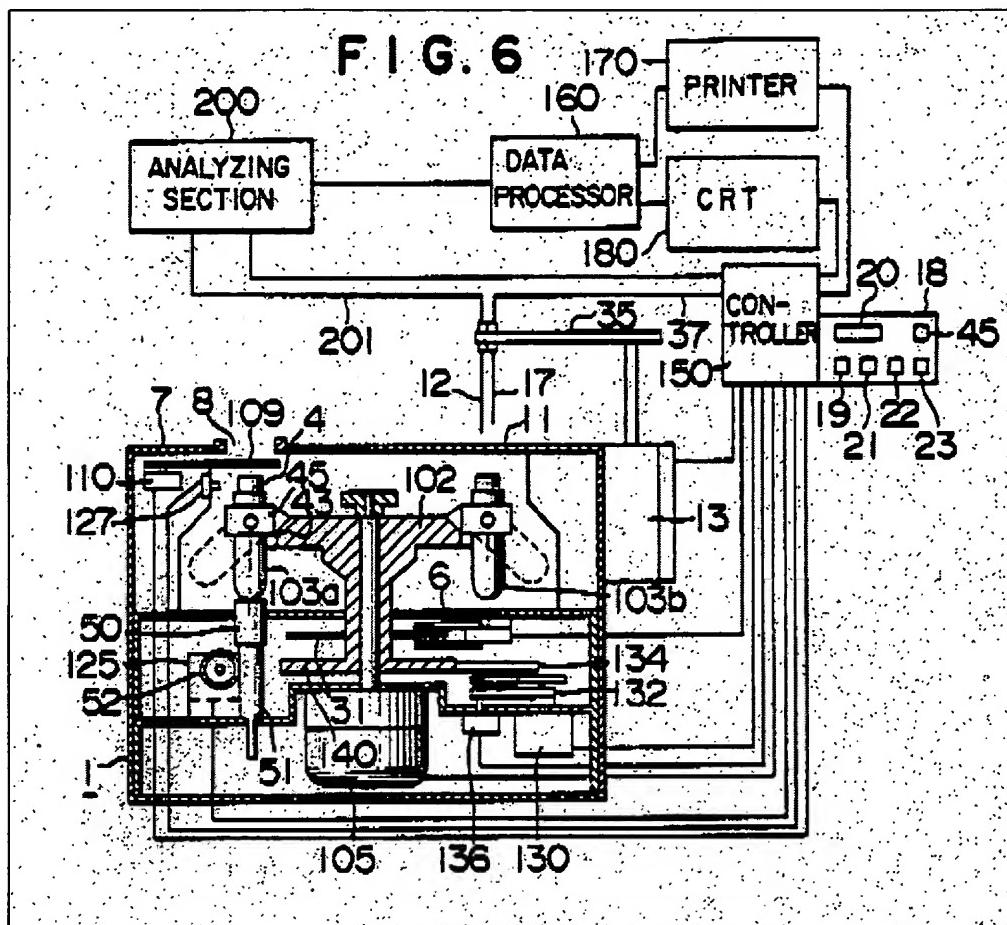


FIG. 2

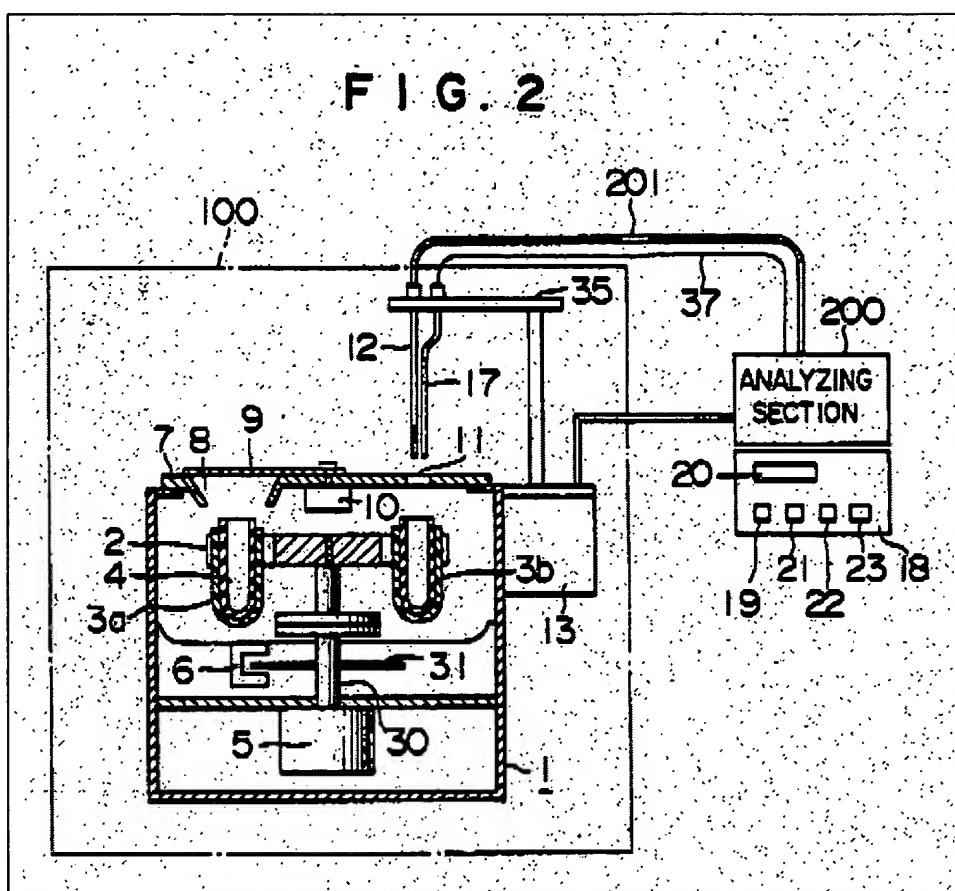
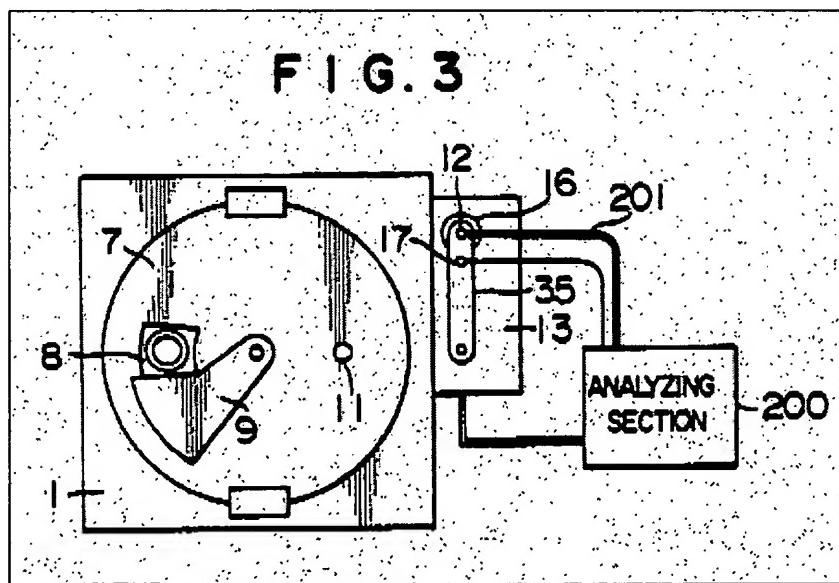


FIG. 3

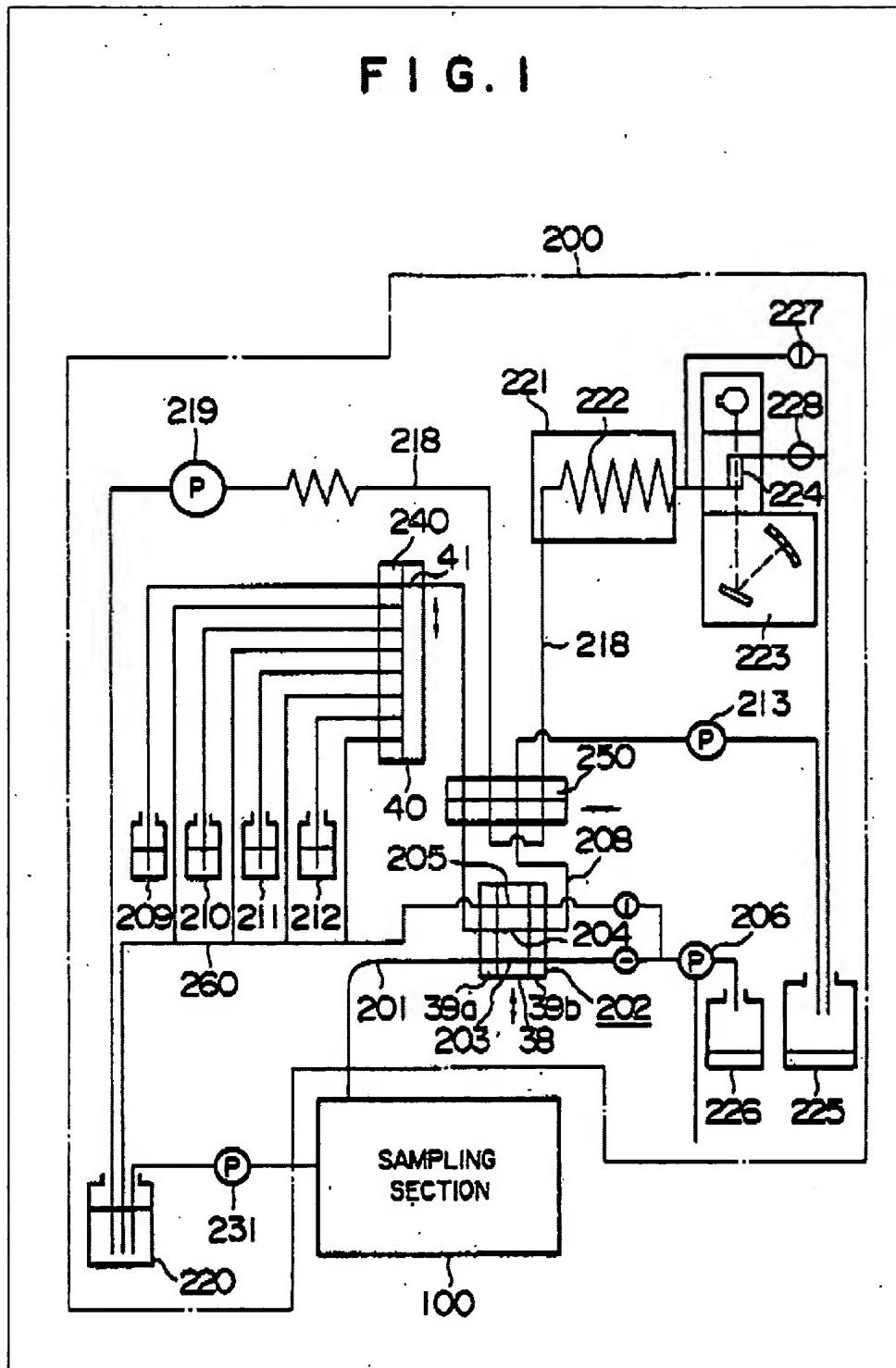


Regarding claims 5 & 35, Yoshida teaches the incorporation of a reference index (e.g., disk 31 & pot detector 127), which facilitates rotor positioning (see col. 3, lines 29 – 48; figures 2 & 6).

Regarding claims 6 – 8, Yoshida teaches the incorporation of a motor (driving device 5) (see col. 3, lines 29 – 48).

Regarding claims 29 – 31, 33, 34, 36 – 38, 42 & 43, Yoshida teaches the incorporation of a controller (150) comprising a microcomputer for operating the disclosed apparatus (see col. 7, lines 9 – 16).

Regarding claims 49, 53 & 54, Yoshida teaches the incorporation of an analyzing section (200) comprising a specimen collector (e.g, flow cell 224), which collects a specimen for analysis (see col. 5, line 35 – col. 63; figure 1).



Regarding claim 46, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3).

Regarding claim 57, Yoshida teaches an apparatus comprising: sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); various sample processing components (e.g., sample take-out pipe 12 & sensing electrode 17); various hoses (e.g., sample transfer pipe 201), which inherently have tips or ends; various pumps (206, 213, 219 & 231); a fluid source (e.g., reagent reservoirs 209 – 212); a specimen collector (e.g., flow cell 224); various switches or valves (e.g., switching valves 240, 250, movable valve 40, slide valve 202); a waste dump (e.g., washing tube 16) (see col. 3, line 1 - col. 7, line 64; figures 1 – 3 , 6 & 7).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 10 – 13, 15, 17, 18 & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Pang et al. (U.S Pat. No. 6,060,022 A) (hereinafter “Pang”).

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Regarding claims 10 – 13, 15, 17, 18 & 23, Yoshida does not specifically teach the incorporation of a sample cluster configuration. As evidenced by Pang, the use of a clustered sample holding configuration with automated centrifuge systems is well known in the art (see col. 20, line 59 – col. 21, line 3; figures 11A – 11D). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a clustered configuration with an automated centrifuge system (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a clustered configuration with an automated centrifuge system.

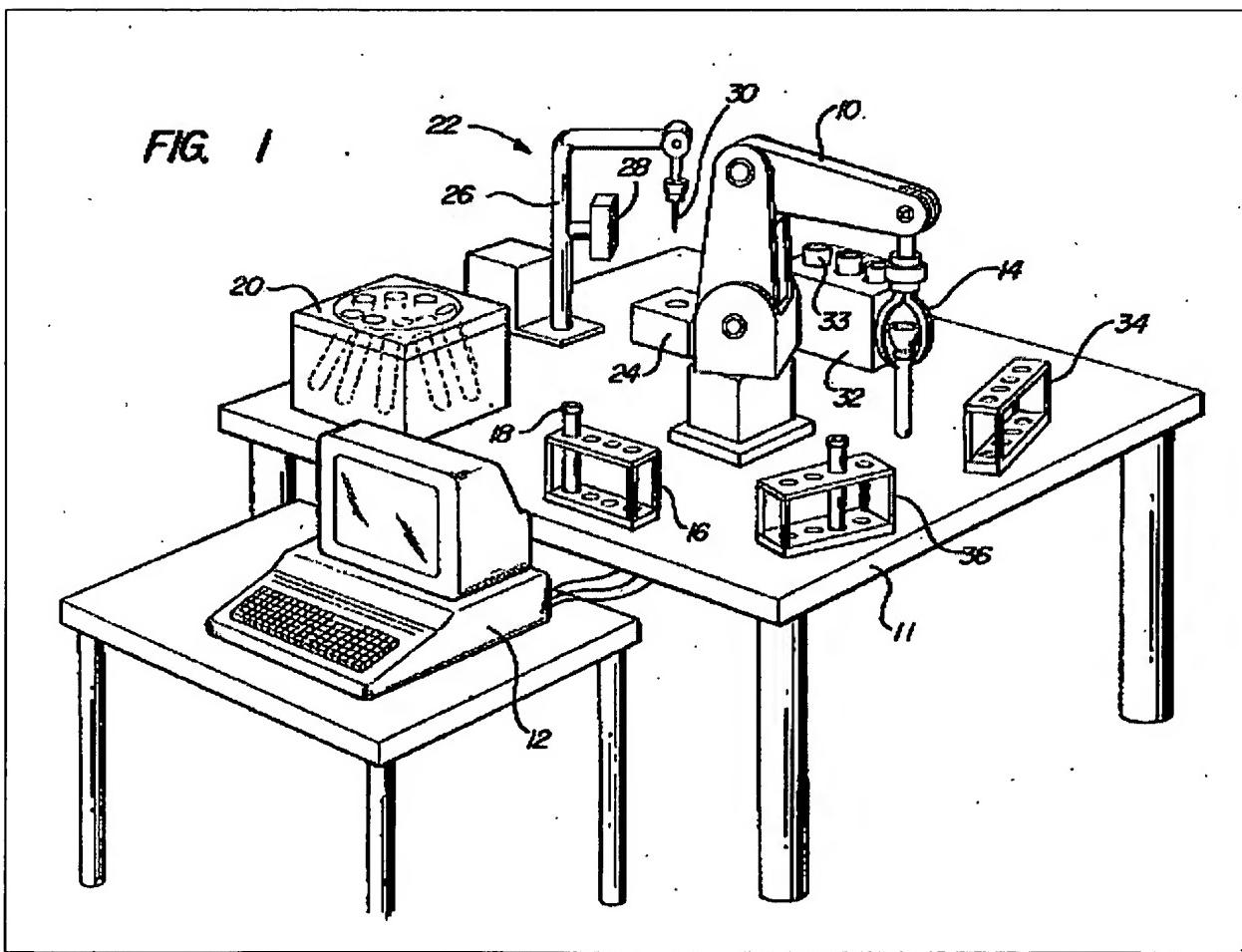
2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Alam et al. (U.S Pat. No. 5,792,050 A) (hereinafter “Alam”).

Regarding claim 22, Yoshida does not specifically teach the incorporation of a sonication apparatus. Although Yoshida does teach the incorporation of a fluid transfer tube (e.g., sample transfer pipe 201 & sample take-out pipe 12) (see col. 3, line 29 – col. 6, line 57; figures 2 & 3). Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Alam, the use of sonication probes in assisting in the biochemical analysis of blood samples is well known in the art (see col. 6, lines 55 – 65). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of utilizing a sonication device in facilitating the analysis of blood samples. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the Courts have held that to provide a mechanical or automatic means to replace manual activity, which accomplishes the same result, is within the ambit of a

person of ordinary skill in the art. See *In re Venner*, 120 USPQ 192 (CCPA 1958). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of sonication devices and fluid transfer tubes as claimed with the disclosed apparatus.

3. Claims 24, 25 & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Roginski et al. (U.S Pat. No. 4,927,545) (hereinafter "Roginski").

Regarding claim 24 & 25, Yoshida does not specifically teach the incorporation of a robot comprising a gripper mechanism. Roginski teaches an apparatus comprising a robotic arm (10) including a gripper (14) for transporting test tubes (18) to and from a centrifuge (20) for facilitating blood sample analysis (see col. 3, line 29 – col. 4, line 65; figure 1).



Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a robotic arm with an automated blood analysis apparatus. As evidenced by Roginski, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a robotic arm mechanism with an automated analytical apparatus comprising a centrifuge. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a robotic arm as claimed with the disclosed apparatus.

Regarding claim 41, Alam teaches the incorporation of a recognition means (e.g., barcode reader 28, 78 & optical sensor 24) (see col. 1, line 29 - col. 8, line 36).

4. Claims 26 – 28 & 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Pang and Roginski.

Regarding claims 26 – 28 & 45, Yoshida does not specifically teach the incorporation of a sample cluster configuration and including a second rotor. As evidenced by Pang, the use of a clustered sample holding configuration with automated centrifuge systems is well known in the art (see col. 20, line 59 – col. 21, line 3; figures 11A – 11D). Furthermore, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a clustered configuration with an automated centrifuge system (see MPEP § 2143.02).

Yoshida does not specifically teach the incorporation of a robotic mechanism. Roginski teaches an apparatus comprising a robotic arm (10) including a gripper (14) for transporting test tubes (18) to and from a centrifuge (20) for facilitating blood sample analysis (see col. 3, line 29

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– col. 4, line 65; figure 1). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a robotic arm with an automated blood analysis apparatus. As evidenced by Roginski, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a robotic arm mechanism with an automated analytical apparatus comprising a centrifuge.

Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a clustered configuration with an automated centrifuge system and including a robotic arm as claimed with the disclosed apparatus.

5. Claims 39 & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Taylor (U.S Pat. No. 4,822,331) (hereinafter “Taylor”).

Regarding claims 39 & 40, Yoshida does not specifically teach the incorporation of operator safety members. As evidenced by Taylor, the incorporation of safety mechanisms with laboratory equipment comprising a centrifuge is well known in the art. Taylor does teach the incorporation of a safety member (e.g., motor 103, clutch 160, stop sleeve 171, relay 154, contact 151, run switch 59 & stop switch 185) with a centrifuge apparatus (see col. 8, line 3 – col. 11, line 20). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a safety mechanism as claimed with the disclosed apparatus, in order to provide safe operation.

6. Claims 47 & 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida.

Regarding claim 47, Yoshida teaches the incorporation of a rinsing or washing means (e.g, washing tube 16) (see col. 4, lines 5 – 17; figure 3). Yoshida does not indicate the incorporation of two bins, tubes or containers and a runoff ramp. The Courts have held that the

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mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to incorporate two containers for rinsing.

The use of ramps for directing fluid flow are well known in the art (see MPEP 2144.03). Therefore, it would have been obvious to incorporate a runoff ramp with the disclosed apparatus for facilitating runoff fluid flow.

Regarding claim 56, the incorporation of second transport mechanism with the disclosed apparatus would have been obvious to a person of ordinary skill in the art.

7. Claims 50 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Feldman (U.S Pat. No. 5,445,958 A) (hereinafter “Feldman”).

Regarding claims 50 – 52, Yoshida does teach the incorporation of a sample analyzing section (200) (see col. 5, lines 35 – 46). Yoshida does not specifically teach the incorporation of a sample purification apparatus comprising a nickel-chelate resin. Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Feldman, the use of liquid column chromatography utilizing a nickel-chelate resin, such as a chelating sepharose resin comprising immobilized iminodiacetic acid groups, in the separation and analysis of blood plasma samples is well known in the art (see col. 4, line 29 – col. 8, line 55). In addition, the Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a separation component as claimed with the disclosed apparatus.

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***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered, but are moot in view of the new ground(s) of rejection.

Prosecution is reopened.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian J. Sines".